

→ SAB

Walk, Roger A.

From: Patskan, George J.
Sent: Thursday, June 05, 2003 5:05 PM
To: Tricker, Anthony; Koller, Debbie; Sanders, Edward; Roemer, Ewald; Tewes, Franz; Haussmann, Hans-Juergen; Roethig, Hans; Bugg, Joy J.; Podraza, Ken F.; Rustemeier, Klaus; Schorp, Matthias; Sarkar, Mohamadi; Vanscheeuwijk, Patrick; Terpstra, Piter; Jupe, Richard; Solana, Rick P.; Dempsey, Ruth; Tafur, Susan S.; McKinney, Willie J; Schramke, Heike; Diekmann, Joerg; Weber, Susanne; Miert, Erik Van
Cc: Baird, Annette M.; Barbara Rapkowitz; Brigitte Viol; Richard Carchman (walntz@msn.com); Walk, Roger A.; Cash, Rose B.
Subject: UNTITLED.PPT
DSS:

Attached is a revised agenda for the SAB meeting.

I was not sure when the best times would be for breaks, lunch etc. so I listed just the duration of the presentation including time for questions.

The main purpose of the meeting is now to discuss certain principles of testing as opposed to a specific product launch/ exposure evaluation. Therefore the data on SCoR will serve to illustrate some the questions and provide a context and data to help us reach some conclusions.

I think the two main questions (there will be others) are:

1. What are the proper references to achieve a goal of harm reduction?
2. When is a change an increase of concern or a substantial decrease?

Topics that relate to these questions include:

- manufacturing variation
- what is the right reference for studies of a specific product
- what background data is needed (e.g. brands study, TES)
- what statistical tests can be used

The discussion time at the end of the day on June 10 is meant to engage the SAB in a way to elicit any suggestions/helpful advise they may have. It will be different format from previous SAB meetings. This discussion period is also an opportunity for PM personnel to contribute their ideas; however, I don't want us to dominate the conversations. We will find out if this is a useful format.

Any time left at the end of the day will be used for a SAB closed session.

I wish we had more time to discuss this before the meeting. I will try to send my revised presentation out tomorrow.

Please let me know if you have comments or suggestions.

Thanks,
George

6/5/2003

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